

REMARKS

The specification has been amended to set forth the complete cross-reference to related applications and to delete the title from page 37, containing the abstract.

Claim 83 has been amended to specify that the concentration step involves ultracentrifugation and to clarify that genomic DNA is extracted from the concentrated microorganisms. Support for the former amendment can be found at page 6, lines 13-15. Claim 92 has been amended to clarify the language by rewriting it in independent form, incorporating the language of claim 83 (from which it originally depended). It is believed that none of these amendments constitute new matter, and their entry is requested.

Applicants thank the Examiner for pointing out the lack of a statement within the specification concerning priority. The specification is amended herein to include such a statement.

Applicants note that an Information Disclosure Statement (IDS) with 43 references was filed on 15 November 2000. Please see the attached copy of the IDS and PTO-stamped postcard receipt. Applicants request the Examiner to return an initialed copy of this IDS with the next paper.

Applicants acknowledge that formal drawings will be required. Formal drawings will be submitted after receipt of a notice of allowance. Because no changes are required in the drawings other than to make them more legible and of better quality, it is believed that a proposed drawing correction is not required at this time. As noted, drawings that fully comply with the rules will be submitted after receipt of a notice of allowance.

The Examiner objected to the specification for presence of the title of the invention on the abstract page (page 37). The specification has been amended to delete the title from that page.

Claims 83, 84 and 92 were rejected under 35 USC §112, second paragraph, for being vague and indefinite. It is believed that the amendments to claims 83 and 92 obviate this rejection, and its withdrawal is therefore requested.

Claim 83 was rejected under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Pitcher et al. (*Lett. Appl. Microbiol.* 8:151-156, 1989). The Examiner contends that Pitcher et al. describes the use of an Eppendorf tube for centrifugation and


that an Eppendorf tube has all of the properties of the ultracentrifuge tube described in claim 83 of this invention. However, it is urged that the ultracentrifuge tube of claim 83 and an Eppendorf tube are not the same. An ultracentrifuge tube differs from an Eppendorf tube in that it can be spun at a much higher rotation rate than an Eppendorf tube, and it is made to withstand a much larger G-force than an Eppendorf tube. Furthermore, claim 83 requires that the concentration be performed by ultracentrifuging the ultracentrifuge tube containing the microorganisms. Pitcher et al. does not disclose ultracentrifugation – it discloses only centrifugation at 1,000 x g. Therefore, it is urged that, because claim 83 describes use of an ultracentrifuge tube (which is not equivalent to an Eppendorf tube) and ultracentrifugation, claim 83 is not anticipated by, or obvious over Pitcher et al, and withdrawal of this rejection is requested.

Claims 83 and 84 were rejected under 35 U.S.C. 103(a) a being unpatentable over Samadpour et al. (*J. Clin. Microbiol.* 31:3179-83, 1993), in view of Pitcher et al. The Examiner states that claims 83 and 84 (which depends on claim 83) are unpatentable in view of the centrifugation taught in Pitcher et al. As detailed above, Pitcher et al. does not teach the claimed elements of an ultracentrifuge tube and ultracentrifugation to concentrate the microorganisms. Therefore, it is urged that because claim 83 describes the use of an ultracentrifuge tube (which is not equivalent to an Eppendorf tube) and ultracentrifugation, claims 83 and 84 are not obvious over Samadpour et al., in view of Pitcher et al. Withdrawal of this rejection is requested.

Claim 92 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pitcher et al., in view of Lanoil et al. (*App. Environ. Microbiol.* 63:1118-23, 1997) and Burgoyne (US 5,756,126). As detailed above, Pitcher et al. does not teach the claimed elements of an ultracentrifuge tube and ultracentrifugation to concentrate the microorganisms. The secondary references do not remedy the deficiencies of Pitcher et al., the primary reference. Therefore, the asserted combination of references do not render claim 92 obvious, and withdrawal of this rejection is requested.

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the cited prior art. Reconsideration of the

instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

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Attachments: Marked-Up Copies of Amendments
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Serial No. 09/666,836
29 October 2001
Mark-ups, Page 1

Marked-up Copy of Specification - Page 1, lines 5-8

The present application is a divisional of U.S. patent application Serial No. 09/571,274, filed 16 May 2000, which is a divisional of U.S. patent application Serial No. 09/265,541, filed 9 March 1999. The present application is further related to U.S. provisional patent application Serial No. 60/077,472, filed 10 March 1998, incorporated herein by reference, and claims priority thereto under 35 USC §119(e).

Marked-up Copy of Specification - Page 37, lines 1-2

[TITLE OF THE INVENTION]

DETECTION AND CHARACTERIZATION OF MICROORGANISMS]

Marked-up Copy of Amended Claims

83 (three times amended). A method for determining a restriction enzyme map of a microorganism, wherein said method comprises the steps of:

- (a) concentrating said microorganism which comprises the steps of:
 - (i) adding a sample containing said microorganism to an ultracentrifuge tube and
 - (ii) [centrifuging] ultracentrifuging said sample in said ultracentrifuge tube to concentrate said microorganism, said ultracentrifuge tube comprising an upper region, a middle region and a lower region wherein an inner diameter of said upper region is larger than an inner diameter of said middle region and wherein an inner diameter of said middle region is larger than an inner diameter of said lower region;
- (b) extracting [said] [genome] genomic DNA from said concentrated microorganism to produce extracted nucleic acid;
- (c) treating said nucleic acid with one or more restriction enzymes to produce fragments of nucleic acid; and
- (d) determining (1) the number of said fragments of nucleic acid, (2) the lengths of said fragments of nucleic acid, or (3) both the number of said fragments of nucleic acid and the lengths of said fragments of nucleic acid.

92. (amended). [The method of claim 83 further comprising the steps of:] A method for determining a restriction enzyme map of a microorganism, wherein said method comprises the steps of:

- (a) concentrating said microorganism which comprises the steps of:
 - (i) adding a sample containing said microorganism to an ultracentrifuge tube and
 - (ii) ultracentrifuging said sample in said ultracentrifuge tube to concentrate said microorganism, said ultracentrifuge tube comprising an upper region, a middle region and a lower region wherein an inner diameter of said upper region is larger than an inner

diameter of said middle region and wherein an inner diameter of said middle region is larger than an inner diameter of said lower region;

(b) extracting genomic DNA from said concentrated microorganism to produce extracted nucleic acid;

(c)[(e)] staining said extracted nucleic acid[, and];

(d)[(f)] immobilizing said extracted nucleic acid on a solid support to produce immobilized nucleic acid[.];

(e) treating said nucleic acid with one or more restriction enzymes to produce fragments of nucleic acid; and

(f) determining (1) the number of said fragments of nucleic acid, (2) the lengths of said fragments of nucleic acid, or (3) both the number of said fragments of nucleic acid and the lengths of said fragments of nucleic acid.

[wherein steps (e) and (f) are performed prior to step (c).]